The Synar Anti-Tobacco Bill Is a Punitive and Radical Measure Intended to Obstruct the Sale and Marketing of a Legal Product

H.R. 2147 would give the FDA virtually unfettered authority to regulate all aspects of the tobacco business, setting forth only *minimum* requirements that the FDA must impose. The bill's so-called "minimum" requirements would:

- impose onerous and unparalleled ingredient labeling requirements and allow the FDA to ban or limit any ingredient on the basis of a vaguely worded and undefined standard;
- classify as "drugs" nontraditional tobacco products and regulate tobacco product ads like prescription drug ads, even though no therapeutic claims are made;
- effectively prohibit the use of objective brand characteristics, such as low-tar/nicotine or nicotine free;
- give the FDA carte blanche authority to dictate the content, form and means of required warnings, as well as mandate any other form and method of public disclosure;
- impose user fees on tobacco companies, based on brand market share, to cover the *full costs* of the proposed regulation;
- give the FDA unprecedented access to *any* tobacco-related document;
- establish a tobacco products advisory committee to act as an anti-tobacco forum;
- create a federal tobacco police force to enforce minimum age laws;
- ban tobacco brand-name sponsorship of any type of event;
- ban sampling to adult smokers who seek samples; and
- lead to conflicting cigarette health warning schemes in the states.

Under the guise of regulating tobacco products like any other product and ensuring product "safety" and disclosure, the Synar bill *unnecessarily* singles out tobacco products for inappropriate and punitive treatment. It is *inappropriate* because the FDA's core function is to ensure product safety, and anti-smoking advocates have repeatedly proclaimed that tobacco products can never be "safe" or "safer." It is *punitive*, as well as *overreaching*, because the bill's "minimum" requirements go far beyond those applicable to other FDA-regulated products. In addition, the bill raises serious First Amendment and public policy concerns.

The true goal of H.R. 2147, despite Rep. Synar's caveat that he does not seek to ban tobacco products, is to accomplish that very result over time, using as a vehicle the complex and unpredictable regulatory scheme created by the bill and the tools available to the FDA and the public under existing food and drug law.

H.R. 2147 Is Both Unnecessary and Inappropriate

- Tobacco products already are extensively regulated by many federal agencies, including HHS, the FTC, BATF, and the Departments of Agriculture and Treasury, as well as by states and localities. With respect to tobacco product ingredients, the major cigarette companies have been providing HHS with an annual list of all ingredients since 1986. And this same law authorizes HHS to review the health effects of such ingredients. Moreover, information about constituent levels in cigarettes is already disclosed to the FTC and the public by voluntary agreement.

- Product safety is not the real purpose of H.R. 2147. The position of anti-smoking advocates is that the "safety" of tobacco products can never be ensured. And, ingredient safety also is not the issue. The government has known the ingredients in cigarettes for almost eight years, and, to date, it has not raised any concerns. Indeed, former HHS Secretary Sullivan testified before a congressional committee that ingredients are a "peripheral" concern and additional regulation is unnecessary.

H.R. 2147 Is Overreaching and Punitive

- H.R. 2147 would require the labeling of *all* ingredients and constituents. Food labeling laws, by contrast, require only a common sense listing of ingredients and one that protects trade secrets. Likewise, constituents arising during the cooking process do not have to be disclosed at all.

- Also unlike food law, the concept that ingredients "generally recognized as safe" ("GRAS") do not warrant FDA preapproval is not part of the Synar bill and, thus, even GRAS ingredients in tobacco products would be subject to a lengthy approval process.

- The FDA's subpoena power over tobacco products would be broader than that which exists for products currently regulated by the Agency.

- Truthful descriptors, such as lower tar, "nicotine free" or "light," would be prohibited, unless the FDA first finds a justifiable impact on the "health" consequences of smoking. Given the government's long-standing policy that, "the health risks of cigarette smoking can only be eliminated by quitting" (Surgeon General's 1981 Report), this provision amounts to an outright ban on the marketing of such products.

- The FDA's broad power to require any kind of public disclosure by any means could require tobacco companies to conduct counteradvertising campaigns against their own products.

- H.R. 2147's user fees are a hidden tax: they bear no resemblance to other existing user fee programs, which are based on the principle that a fee is charged for *benefits* received in the form of particularized services, not for full-fledged regulation.

- The creation of an advisory committee *on tobacco products* with no tobacco representation is unfair on its face.

H.R. 2147 Raises Serious Constitutional and Public Policy Concerns

- Repealing federal preemption of state common law claims based on the inadequacy of the required cigarette warnings would subvert Congress' interest in providing a uniform and understandable cigarette warning scheme. It also would pave the way to state-imposed restrictions on advertising and promotion creating, in the words of the ACLU, "grave constitutional problems."

- Moreover, the FDA's authority to, at any time and by any means, modify the content, and increase the placement and size of warnings as it sees fit undermines the goals (and success) of a congressionally mandated system of warnings.

- Vesting what amounts to *taxing* power to the FDA under the facade of "user fees" challenges basic constitutional principles and sets a dangerous and obvious precedent for other industries.

- Banning brand name sponsorship of any type of event is an unprecedented and inappropriate limit on a corporation's right to associate with and receive recognition from cultural and sporting events it supports.

- Treating tobacco ads like prescription drug ads would be confusing to consumers, since these ads are aimed at physicians. Moreover, the FDA could implement a ban on imagery (*i.e.*, "tombstone" ads). Denying companies the right to differentiate their products flies in the face of the Supreme Court's confirmation that "commercial illustrations are entitled to the First Amendment protections afforded commercial speech."

- Creating a federal police force to enforce minimum age laws hands over to the federal government authority that properly rests with the states.

- Lack of resources and excessive responsibilities already has seriously hampered the FDA's functioning. Placing the FDA in the middle of the highly politicized debate on smoking will tie up the agency in regulatory knots at the expense of its basic work -- ensuring the safety of the nation's food and drug supply.

H.R. 2147 Provides the Mechanism With Which De Facto Prohibition of Tobacco Products May Be Achieved

The bill makes a thinly veiled attempt to stave off the claim that the it is intended to ban tobacco products over time: it prohibits the ban of a tobacco product *solely* on the basis that "tobacco causes disease." However, the system of FDA regulation, as augmented by the Synar bill, provides repeated opportunities to obstruct the sale and marketing of tobacco products. *For example*:

- Since the bill requires that the FDA must find tobacco additives to be "safe" before they can be used, an *instant ban* could be implemented on all products currently on the market pending the Agency's review.

- Even short of an outright suspension or ban on marketing pending review, anti-smoking advocates could use the FDA process, which is subject to manipulation by *any* interested party, to effectively ban certain brands by pressing the FDA to prohibit or restrict key flavor additives.

- Testing of every minute constituent in tobacco smoke, to meet the bill's labeling requirements, would take years to accomplish. In the meantime, tobacco products could not be marketed.

- Low-tar and nicotine products would be driven off the market.

- "Nontraditional" tobacco products would be regulated as drugs, meaning that they couldn't be marketed at all because drugs must have demonstrated therapeutic benefits before they can be sold. This affects not only innovative new products, but conceivably even products on the market today, since the bill leaves it to the FDA to define the term "cigarettes."

- Cigarettes essentially could become unmarketable. The FDA's sweeping power to dictate the content, form and means of required tobacco product warnings and require any other type of public disclosure, combined with the bill's onerous and unparalleled ingredient and constituent disclosure requirements, could lead to the obliteration of the cigarette pack face and reduce ads to a statement that effectively says, *"Don't Buy This Product."*

- The FDA would be empowered to review and censor ads. This would be fertile ground for anti-smoking advocates who could use existing FDA mechanisms to petition the Agency to act, or refrain from acting, on any issue within its jurisdiction.

In conclusion, H.R. 2147 should be recognized for what it is and is intended to be -- a *de facto* ban on tobacco products over time. Congress has declined to do this affirmatively and should similarly decline to do it through the back door.